REMARKS

The present amendment is intended to be fully responsive to the Office Action having a mailing date of March 28, 2007, wherein claims 1, 2, 4-11, 13-17, 19-21, 23-34, 36-42 and 50 have been rejected and are currently pending. By this amendment, claims 1, 7, 16, 20, 26, 33, and 42 have been amended. Thus, claims 1-2, 4-11, 13-17, 19-21, 23-34, 36-42, and 50 remain pending. Applicant submits that no new matter has been added by this amendment and that support for the claims, as amended, may be found throughout the specification and drawings. At least for the reasons set forth below, Applicant respectfully traverses the foregoing rejections. Further, Applicant believes that there are also reasons other than those set forth below why the pending claims are patentable, and reserve the right to set forth those reasons, and to argue for the patentability of claims not explicitly addressed herein, in future papers. Applicants respectfully requests reconsideration of the present application in view of the above amendment, the new claims, and the following remarks.

35 U.S.C. § 102

Claim Rejections Using *Balbierz*

Claims 1, 2, 6, 13-17, 20, 25 and 33 are rejected under 35 U.S.C. § 102(e) as being anticipated by *Balbierz* (U.S. Patent No. 6,869,430). Applicants respectfully traverse the rejection.

A. Claim 1

Claim 1 recites an introducer stylet and a separate target confirmation device. In the Office action, the Examiner contends that Balbierz discloses "an introducer for a plurality of resilient members" whereby the "resilient members . . . constitute a stylet and a target confirmation device." Applicants respectively disagree.

Balbierz discloses a "tissue biopsy and treatment apparatus 10" that is configured for "volumentrically sampling the issue mass and delivering energy or other treatment to produce an ablation volume 5av." Col. 5, lines 25-30. The biopsy treatment apparatus 10 includes an

introducer 12 having a lumen 13 and a plurality of "resilient members 18 positionable within lumens 13". Col. 5, lines 31-34. The distal end 16 of the introducer 12 "may be sufficiently sharp to penetrate tissue . . . " Col. 5, lines 36-37. Thus, Balbierz discloses that the *biopsy device* includes a cannula having lumens into which the "resilient members 18" are positioned. The cannula of the *biopsy device* is used to penetrate tissue, not the resilient members. Nor is there any such disclosure that the resilient members are even capable of penetrating tissue or of "creating a pathway as claimed by Applicants in claim 1.

Nor does Balbierz disclose or even suggest an introducer stylet and a separate target confirmation device. Indeed, the Examiner refers to the same resilient members as serving as both an introducer stylet and target confirmation device. Further, claim 1 specifically requires that the target confirmation device may only be positioned within the cannula when the introducer is removed. As may be seen from the Figures 7-9 of Applicants' invention, both an introducer and the separate target confirmation cannot be placed within the outer cannula at the same time. Indeed, the stylet is used to create a pathway for the target confirmation device. Thus, the resilient members Balbierz cannot be both the introducer stylet and target confirmation device. For this separate reason, Balbierz does not anticipate claim 1.

Further, Balbierz does not disclose or suggest an introducer that may be selectively and *removably* positioned within the lumen of the outer cannula. As may be seen in Applicants' specification, the introducer stylet embodied in claim 1 may be completely removed from the outer cannula to permit introduction of the target confirmation device. Balbierz, however, does not disclose this feature. Instead, Balbierz only discloses that the resilient members may be "advanceable *in and out of distal end 16*." Nowhere does Balbierz teach or suggest that the resilient members may be selectively removed from an inner lumen of an outer cannula to permit an additional and separate target confirmation device to be inserted therein. For this additional reason, claim 1 is patentably distinct from Balbierz.

B. Dependent Claims 2, 6, 13-17, 20, 25, and 33

The dependent claims, namely claims 2, 6, 13-17, 20, 25 and 33 are allowable for Balbierz due to their dependency upon allowable claim 1. However, these claims also contain additional features and limitations that independent define over Balbierz. For example, claim 2 expressly claims that the cannula is configured to introduce at least a biopsy device. However, Balbierz does not disclose a "cannula . . . configured to introduce a biopsy device" as alleged by the Examiner. Indeed, in Balbierz, the cannula is *part of the biopsy device*. Thus, it cannot introduce itself.

Claim 13 recites that a distal end of the introducer stylet includes a tissue piercing member. While this claim was rejected in view of Balbierz, there is no teaching or suggestion that the resilient members include a tissue piercing member.

Claim 16 recites that the target confirmation device includes a proximal end having a first fitting interface that engages and connects to a second fitting interface on the outer cannula upon insertion of the target confirmation device into the outer cannula so as to prevent relative movement between the target confirmation device and the outer cannula. There is no teaching or suggestion in Balbierz of these features.

Claim 20 recites a biopsy device that includes a handpiece and a cutting element, whereby the cutting element is disposed adjacent to a distal end of the biopsy device and defines a tissue-receiving opening for removing tissue from the target site, wherein a portion of the biopsy device is selectively insertable within the cannula after the introducer stylet and target confirmation device are removed from the cannula. These features are also not shown in Balbierz.

Claim 33 recites a tissue resection device including a tissue receiving opening that is positioned in a sidewall of the tissue resection device, wherein the tissue receiving opening is rotatable relative to the cannula. The device in Balbierz provides no disclosure of a tissue resection device having a tissue receiving opening in a sidewall of the tissue resection device. Nor does it provide any disclosure that the tissue receiving opening is rotation relative to the cannula. The passage of Balbeirz cited by the Examiner, namely col. 17, lines 57-63 does not discuss these features. Indeed, these passages are directed to a collection device, not a tissue receiving opening located adjacent a distal end thereof.

35 U.S.C. § 103

Claim Rejections Using *Balbierz* and *Hurtak*

Claims 4, 5, 8-11, 19, 26, 28, 34, 42 and 36-39 were recited as being rejected under 35 U.S.C. 103(a) as being unpatentable over *Balbierz* ("430) in view of *Hurtak* (WO 98/55016). Applicants respectfully traverse the rejection.

As an initial matter, Applicant notes that no analysis is provided of the alleged rejections of claims 7-9 or the independent claim 26. Thus, it is not clear as to how independent claim 7 is rejected as being obvious in view of the Balbierz and Hurtak combination. The features of claim 9 are also not taught in Hurtak as there is certainly no mention of distal end of a target confirmation device having a predetermined shape that is distinguishable.

With respect to independent claim 26, which is a method claim, the only analysis that Applicants can discern that relates to this claim is the Examiner's statement that "it is well known in the art that, during minimally invasive interventional procedures, both a stylet and guidewire may be sequentially disposed within a catheter or cannula in order to reach a target site within the body . . ." The Examiner appears to be taking judicial notice. Applicants respectfully request a citation to prior art references to support this contention.

Further, even if the Examiner's statement is correct, the claimed introducer stylet in claim 26 is used to create a pathway to a target area, while simultaneously delivering an outer cannula into the body. The introducer stylet is then removed, leaving behind the outer cannula and holding open the pathway for introduction of the target confirmation device. Further, the introducer stylet must be completely removed before insertion of the target confirmation device. These features are not taught in either Bablierz or Hurtak or a combination thereof.

Further, the arguments presented above in connection with the §102 rejections are equally applicable here. And Hurtak does not make up for the deficiencies of Balbierz. Indeed, Hurtak

only teaches a medical guidewire for use in intravascular medical procedures upon which catheters are positioned over and slid over through a vascular system.

Thus, for at least the reasons set forth above, the claims patentably define over the combination of Balbierz and Hurtak.

Claim Rejections Using *Balbierz Hurtak, and Werne*

Claims 21, 23, 24, 27, 29-32, 41 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Bablierz* ("430) in view of *Hurtak* ('016), further in view of *Werne* ('5,782,764). Applicants traverse the rejection.

The arguments above in connection with both the §102 and §103 rejections are applicable here, as well. Moreover, Applicants respectfully disagree with the Examiner's characterization of the teachings of the Bablierz/Hurtak/Werne combination. For example, the Examiner states on page 5 that Werne teaches a cutting element with a guidewire disposed therein, referencing Figs. 8-10. However, the specification of Werne discloses that Figure 8 shows a "marker stylet 142" having a "contrast agent 146" encapsulated in a chamber in the marker stylet. Thus, Werne actually teaches away from a guidewire, and, in fact, teaches away from using a separate introducer stylet and target confirmation device. Indeed, Applicants have previously pointed to this distinguishing feature stated in a previous office action:

"Claim 1, as amended, requires a separate target confirmation device. The target confirmation device is insertable within the cannula when the introducer is removed. This feature is also not shown in Werne."

And the Examiner expressly recognized this difference in removing the previous rejection under Werne. Accordingly, claims 21, 23, 24, 27, 29-32, 41 and 50 patentably define over the cited references.

CONCLUSION

Reconsideration and allowance are respectfully requested. In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-0013, under Order No. 65937-0037 from which the undersigned is authorized to draw.

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Respectfully submitted,

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